

**REMARKS**

Claims 56, 69, 71, 107, 110 and 112, as amended, and new claims 113-130 are pending in this application for the Examiner's review and consideration, upon entrance of this paper. Claims 1-55, 57-68, 70, 72-106, 108-109, and 111 have been canceled without prejudice to the Applicants' right to file one or more divisional, continuation, or continuation-in-part applications with claims directed to any canceled subject matter. Applicants have amended claims 56 and 107 to recite that 3'-azido-3'-deoxy-5'-(3-dodecanamido-2-decyloxypropyl)-phosphothymidine and 3'-azido-3'-deoxy-5'-(3-dodecyloxy-2-decyloxypropyl)-phosphothymidine, respectively, can be used in methods of treatment of viral infections caused by the viruses: HIV-1, herpes virus, influenza, respiratory syncytial virus, mumps, measles, and parainfluenza virus. *See* Specifications, page 14, line 20 to page 15, line 11. New claims 113-130 are supported by the application as originally filed as set forth in the table below. No new matter has been added by the amendments.

<b><u>Claim Number</u></b>	<b><u>Support in the Specification</u></b>
113 and 122	<i>See</i> Example 9, page 25.
114 and 123	<i>See, for example</i> , Specification at page 15, line 24.
115 and 124	<i>See, for example</i> , Specification at page 15, line 24.
116 and 125	<i>See, for example</i> , Specification at page 15, line 25.
117 and 126	<i>See, for example</i> , Specification at page 15, line 25.
118 and 127	<i>See, for example</i> , Specification at page 15, line 25.
119 and 128	<i>See, for example</i> , Specification at page 15, lines 25-26.
120 and 129	<i>See, for example</i> , Specification at page 18, lines 11-16.
121 and 130	<i>See, for example</i> , Specification at page 18, lines 11-16.

**I. The Rejection under 35 U.S.C. § 112 Second Paragraph Should be Withdrawn**

Claims 107 and 110-112 are rejected under 35 U.S.C. § 112, second paragraph, for reasons set fourth on pages 2-3 of the Office Action. Specifically, the office action alleges that the claims are vague and indefinite as the nomenclature of the species is missing the point of attachment of the dodecyloxy.

Applicants have amended claim 107 to correct a typographical error. Claim 107 now recites the compound 3'-azido-3'-deoxy-5'-(3-dodecyloxy-2-decyloxypropyl)-phosphothymidine. (See specification at paragraph [0103]).

Applicants respectfully request that the rejections of claims 107, 110 and 112 under 35 U.S.C. § 112, second paragraph, be withdrawn.

## **II. The Rejection under 35 U.S.C. § 103(a) Should be Withdrawn**

Claims 56, 69-71, 107 and 110-112 are rejected under 35 U.S.C. § 103(a) for reasons set forth on pages 3-4 of the Office Action. Specifically, the Examiner alleges that WO 91/19726 to Piantadosi *et al.* ("Piantadosi") encompasses the instantly claimed compounds for the same uses as claimed herein, based on choosing a specific selection of ten different substituents at ten substitution sites. The Examiner alleges that the compounds of the instant invention are generically embraced by Piantadosi in view of the interchangeability of the substitutions of the phospholipids. Consequently, the Examiner alleges one of ordinary skill of the art would have been motivated to combine the specific substituents and thus would have obtained the instantly claimed compounds. Applicants respectfully traverse this rejection for the following reasons.

As the Examiner is aware, the proper inquiry for obviousness is whether the references disclose each and every feature of the claim and whether the references suggest the invention and provide one of ordinary skill in the art with a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991); *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988); *In re Royka*, 409 F.2d 981, 180 USPQ 580 (CCPA 1974); and M.P.E.P. § 2143.03. Furthermore, in asserting an obviousness rejection of a species when the prior art teaches a genus, the fact that a claimed species or subgenus is encompassed by a prior art genus is insufficient by itself to establish a *prima facie* case of obviousness. See *In re Baird*, 16 F.3d 380, 382 (Fed. Cir. 1994); and M.P.E.P. § 2144.08. In addition some motivation to select the claimed species must be taught by the prior art. M.P.E.P. § 2144.08.

Piantadosi teaches ether lipid-nucleosides. See Piantadosi at page 2, lines 12-13. Each of these ether lipid nucleosides is encompassed by Formulas I, II and III. *Id.* at page 2, line 13 through page 6, line 7. For each of these formulas, there are ten or more substitution

sites.<sup>1</sup> See page 2, line 13 through page 6, line 7. For each of these substitution sites, there are between two to more than 20 different substituents. See e.g. page 5, lines 27-38.

Piantadosi further teaches that these nucleosides may be antiviral and be used to treat an HIV-1 infection. See page 10, lines 28-29; page 15, line 4-5.

Piantadosi does not render independent claim 56 obvious since Piantadosi does not provide the legally required motivation to modify the disclosure of the reference to teach the claimed invention nor does Piantadosi provide a reasonable expectation of success. Specifically, Piantadosi does not disclose or suggest that 3'-azido-3'-deoxy-5'-(3-dodecanamido-2-decyloxypropyl)-phosphothymidine, or a pharmaceutical salt thereof effective in combating HIV-1, herpes virus, influenza, respiratory syncytial virus, mumps, measles, and parainfluenza virus. Piantadosi simply discloses a vast genera of compounds that may be used to combat an HIV-1 infection. See page 15, lines 4-6. Specifically, Piantadosi discloses a genus that encompasses over 2.1 million possibilities for ether lipid-nucleosides according to Formula I.<sup>2</sup> (Emphasis added). And as the Examiner is aware, the Federal Circuit has held "a prior art reference that disclosed a generic formula encompassing a claimed composition would not have provided the requisite motivation to select that composition because the reference (a) disclosed a 'vast number' of possibilities. . ." *In re Baird* 16 F.3d 380 (Fed. Cir. 1994). Moreover, even though Piantadosi discloses a small number of illustrative compounds, there is no motivation to select the individual substituents from the generic disclosure of Piantadosi to thereby suggest 3'-azido-3'-deoxy-5'-(3-dodecanamido-2-decyloxypropyl)-phosphothymidine without using the pending claims as a blue print to pick and chooses the claim elements from the cited reference. Indeed, in *In re Wesslau* (1965), the CCPA cautioned that "it is impermissible within the framework of §103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." In addition, in *In re Wright* (1989), the Office's attempt to show a suggestion of the claimed invention consisted

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<sup>1</sup> Applicants note that as used herein in "substitution sites" includes sites specifying the number of repeating units such as e.g.  $-(PO_3^-)_n$ ,  $-(PO_3^-)_m$ ,  $-(CH_2)_m$ . See Piantadosi, Formula I at page 2; Formula II at page 3; Formula III at page 5

<sup>2</sup> The total number of possible ether lipid-nucleoside was calculated based on the number of possible substituents at each substitution site. Number of possible substituents were as follows:  $R_1 = > 10$ ;  $R_2 = > 20$ ;  $W_1 = 4$ ;  $W_2 = 5$ ;  $n = 2$ ;  $X_1 = 2$ ;  $X_2 = 2$ ;  $Y = 3$ ;  $Z = 2$ ;  $B = 11$ . Total number of possible choices are  $10 \times 20 \times 4 \times 5 \times 2 \times 2 \times 2 \times 3 \times 2 \times 11 = 2,112,000$ .

of taking statements wholly out of context and giving them meanings they would not have had to one skilled in the art having no knowledge of applicant's invention, or for that matter to anyone else who can read the specification with understanding.

One of ordinary skill in the art simply would not have a reasonable expectation that 3'-azido-3'-deoxy-5'-(3-dodecanamido-2-decyloxypropyl)-phosphothymidine, or a pharmaceutical salt thereof is effective in combating HIV-1, herpes virus, influenza, respiratory syncytial virus, mumps, measles, and parainfluenza virus based on the disclosure of Piantadosi.

Since claims 69 and 71 depend from claim 56 and include all the features of claim 56, claims 69 and 71 are not rendered obvious for at least the same reasons that independent claim 56 is not rendered obvious.

Piantadosi does not render independent claim 107 obvious because Piantadosi does not provide the legally required motivation to modify the disclosure of the reference to teach the claimed invention nor does Piantadosi provide a reasonable expectation of success. Specifically, Piantadosi does not suggest that 3'-azido-3'-deoxy-5'-(dodecyloxy-2-decyloxypropyl)-phosphothymidine or a pharmaceutical salt thereof is effective in combating HIV-1, herpes virus, influenza, respiratory syncytial virus, mumps, measles, and parainfluenza virus. *See* Specification at page 14, line 20 to page 15 line 7.

For at least the reasons discussed above for claim 56, Piantadosi does not render claim 107 obvious.

Since claims 110 and 112 depend from claim 107 and include all the features of claim 107, claims 110 and 112 are not rendered obvious for at least the same reasons that independent claim 107 is not rendered obvious.

Applicants have cancelled claims 70 and 11 thereby rendering the rejection of these claims under 35 U.S.C. § 103(a) moot.

For the above reasons, Applicant respectfully requests that the rejection of claims 56, 69-71, 107 and 110-112 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

### **III. The Double Patenting Rejection Should be Withdrawn**

The Examiner rejected claims 56, 70, 107 and 111 for obviousness-type double patenting as being obvious over claims 1-3, 8, 9, 33-36 and 41-43 of U.S. Patent No. 6,030,960 ("the '960 patent"). Specifically, the Examiner alleged "[a]lthough the conflicting

claims are not identical, they are not patentably distinct from each other because U.S. '960 embraces the method of use of the compounds of claims 56 and 107..."

Applicants submit herewith a Terminal Disclaimer disclaiming the terminal part of any patent granted on the above identified application, which would extend beyond the expiration date of U.S. Patent No. 6,030,960. For the above reason, Applicants respectfully request that the double patenting rejection be reconsidered and withdrawn.

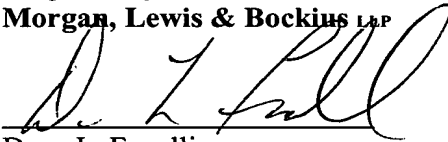
**IV. Conclusions**

It is respectfully submitted that all claims are now in condition for allowance, early notice of which would be appreciated. Should the Examiner disagree, Applicants respectfully request a telephonic or in-person interview with the undersigned attorney to discuss any remaining issues and to expedite the eventual allowance of the claims.

No fee is believed to be due with this Amendment. Should any fee be required, however, please charge such fee to Morgan, Lewis & Bockius LLP Deposit Account No. 50-0310.

Dated: December 22, 2005  
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Respectfully submitted,  
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